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K2M Expands Degenerative Product Offering with 510(k) Clearance for EVEREST Spinal System

LEESBURG, VA … April 27, 2011 – K2M, Inc., a spinal device company developing innovative solutions for the treatment of complex spinal pathologies, today announced at the International Society for the Advancement of Spine Surgery (SAS) Conference that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market the EVEREST Degenerative Spinal System, a versatile top-loading polyaxial pedicle screw system featuring the ability to accommodate multiple levels of fixation rigidity to help surgeons individualize patient care. The system provides for both titanium and cobalt chrome rods of two different diameters, 5.5 and 6.0 mm, limiting inventory and increasing adaptability.

EVEREST is designed to maximize both osteoporotic and dense bone fixation and the modified square thread of the locking set screw may reduce the potential for cross-threading. Additionally, the mixed material screw head minimizes splay compared to a screw head made entirely of titanium, which improves the biomechanical performance of the construct.

“A combined team of surgeons and engineers worked closely together to design the EVEREST Degenerative Spinal System, which utilizes both titanium and cobalt chrome and optimizes thread pitch for use in both osteoporotic and dense bone fixation,” stated Dr. John Carbone, Orthopedic Surgeon at Harborview Reconstructive Spine & Orthopedic Specialists. “In my opinion, the strength, range of motion, and stiffness of EVEREST provide surgeons the intraoperative flexibility to address a variety of surgical pathologies.”

“FDA clearance for EVEREST is an important expansion of our product offering for treating Degenerative Disc Disease (DDD), as well as more complex pathologies,” stated Eric Major, K2M’s President and CEO. “EVEREST is a next generation system inspired by the lessons learned from our expanding product portfolio and has been designed to be a best-in-class degenerative fixation system.”

About K2M

K2M, Inc. is an innovative spinal device company committed to the research, development, and commercialization of simplified solutions for the treatment of complex spinal pathologies and procedures. The company is recognized as a worldwide leader in providing unique technologies for the treatment of deformity, degenerative, trauma, and tumor spinal patients. K2M’s complete portfolio of next generation products includes: spinal stabilization systems, minimally invasive systems, and other advancing technologies such as motion preservation, annular repair, and nucleus replacement. Additional information is available online at www.K2M.com.

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